

10/517122

DT Rec'd PCT/PTO 02 DEC 2004

Dkt. #691-C-PCT(CN)-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : JIN, et al.

U.S. Serial No. : Not Yet Known, corresponding to International Application No. PCT/CN03/00431, filed June 3, 2003, which claims priority of U.S. Serial No. 10/291,327, filed November 8, 2002; U.S. Serial No. 60/418,100, filed October 11, 2002; U.S. Serial No. 60/384,971, filed June 3, 2002

Filed : Herewith

For : HAZARD-FREE MICROENCAPSULATION FOR STRUCTURALLY DELICATE AGENTS, AN APPLICATION OF STABLE AQUEOUS-AQUEOUS EMULSION

Law Offices of Albert Wai-Kit Chan, LLC  
World Plaza, Suite 604  
141-07 20<sup>th</sup> Avenue  
Whitestone, New York 11357

December 2, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Mail-Stop Patent Application

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following references which are listed below and on Forms PTO/SB/08A and PTO/SB/08B, which are attached hereto as **Exhibit A and Exhibits 26 and 28**.

1. Patent No. 5,716,644, Zale, S. E., Burke, P. A., Bernstein, H., Brickner, A., for COMPOSITION FOR SUSTAINED RELEASE OF NON-AGGREGATED ERYTHROPOIETIN (February 10, 1998).

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2. PCT Application, WO 96/40071, Neocrin Company, for METHOD FOR THE MANUFACTURE OF MINIMAL VOLUME CAPSULES CONTAINING BIOLOGICAL MATERIAL (1996).
3. US Patent Application, U.S. Serial No. 09/886,555, Jin, Tuo, Li Chen, and Hua Zhu, for STABLE POLYMER AQUEOUS/AQUEOUS EMULSION SYLSTEM AND USES THEREOF (2001).
4. Langer, R., Folkman, J., "Polymers for the sustained release of proteins and other macromolecules," Nature 263, 797-800 (1976).
5. CAS, Results of search on chemical abstracts on the subject of sustained release of proteins based on degradable polymers." (2002).
6. Weert, M. v., Hennink, W. E., Jiskoot, W., "Protein instability in poly(lactic-co-glycolic acid) microparticles," Pharm. Res. 17, 1159-1167 (2000).
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8. Burke, P. A., "Controlled release protein therapeutics: effects of process and formulation on stability," Handbook of pharmaceutical controlled release technology, Marcel Dekker, 661-692 (2000).
9. Cleland, J. L., Jones J.S., "Stable formulations of recombinant human growth hormone and interferon- $\gamma$  for microencapsulation in biodegradable mircospheres," Pharm. Res. 13, 1464-1475 (1996).

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10. Johnson, O. L., "The stabilization and encapsulation of human growth hormone into biodegradable microspheres," *Pharmaceutical Research* 14, 730-735 (1997).
11. Cunningham, B. C., Mulkerrin, M. G., Wells, J. A., "Dimerization of human growth hormone by zinc," *Science* 253, 545-548 (1991).
12. Sanchez, A., Villamayor, B., Guo, Y., McIver, J., Alonso, M. J., "Formulation strategies for the stabilization of tetanus toxoid in poly(lactide-co-glycolide) microspheres," *Intern. J. Pharm.* 185, 255-266 (1999).
13. Schwendeman, S. P., Tobio, M., Jaworowicz, M., Alonso, M. J., Langer, R., "New strategies for the microencapsulation of tetanus vaccine," *J. Microencapsulation* 15, 299-318 (1998).
14. Morlock, M., Koll, H., Winter, G., Kissel, T., "Microencapsulation of rh-erythropoietin, using biodegradable poly(D,L-lactide-co-glycolide):protein stability and the effects of stabilizing excipients," *European Journal of Pharmaceutics and Biopharmaceutics* 43, 29-36 (1997).
15. Yoshioka, S., Aso, Y., Kojima, S., "Dependence of the molecular mobility and protein stability of freeze-dried  $\gamma$ -globulin formulations on the molecular weight of dextran," *Pharmaceutical Research* 14, 736-741 (1997).
16. Weert, M. v. d., Hof, R. v., Weerd, J. v. d., Heeren, M.A., Posthuma, G., Hennink, W. E., Crommelin D. J. A., "Lysozyme distribution and conformation in a biodegradable polymer matrix as determined by FTIR techniques," *J. Controlled Release* 68, 31-40 (2000).

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17. Morita, T., Horikiri, Y., Suzuki, T., Yoshino, H., "Preparation of gelatin microparticles by co-lyophilization with poly(ethylene glycol): characterization and application to entrapment into biodegradable microspheres," International Journal of Pharmaceutics 219, 127-137 (2001).
18. Maa, Y.-F., Nguyen, P-A., Hsu, S. W., "Spray-drying of air-liquid interface sensitive recombinant human growth hormone," J. Pharm. Sci., 87, 152-159 (1998).
19. Morita, T., Horikiri, Y., Yamahara, H., Suzuki, T., Yoshino, H., "Formation and isolation of spherical fine protein microparticles through lyophilization of protein-poly(ethylene glycol) aqueous mixture," Pharm. Res. 17, 1367-1373 (2000).
20. Park, T. G., Lee, H.Y., Nam, Y.S., "A new preparation method for protein loaded poly(D,L-lactic-co-glycolic acid) microspheres and protein release mechanism study," J. Controlled Release 55, 181-191 (1998).
21. Franssen, O., Hennink, W. E., "A novel preparation method for polymeric microparticles without the use of organic solvents," Intern. J. Pharm., 168, 1-7 (1998).
22. Schwendeman, S. P., Cardamone, M., Brandon, M. R., Klibanov, A., Langer, R., "Stability of proteins and their delivery from biodegradable polymer microspheres," S. C. H. Bernstein, Ed., Microparticulate Systems for the Delivery of Proteins and Vaccines, (Mercele Dekker, New York, 1996), vol. 77, 1-49.

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23. Liu, W. R., Langer, R., Klibanov, A. M., "Moisture-induced aggregation of lyophilized proteins in the solid state," *Biotech. Bioeng.* 37, 177-184 (1991).
24. Bittner, B., Morlock, M., Koll, H., Winter, G., Kissel, T., "Recombinant human erythropoietin (rhEPO) loaded poly(lactide-co-glycolide) microspheres: influence of the encapsulation technique and polymer purity on microsphere characteristics," *Eur. J. Pharm. Biopharm.* 45, 295-305 (1998).
25. Takahata, H., Lavelle, E.C., Coombes, A.G.A., Davis, S.S., "The distribution of protein associated with poly(DL-lactide co-glycolide) microparticles and its degradation in simulated body fluids," *J. Controlled Release* 50, 237-246 (1998).
26. PCT International Search Report for JIN, et al, Int'l Application No. PCT/CN/00431, Filed June 3, 2003, Dated August 1, 2003. [**Exhibit 26**]
27. C.N. Patent No. 1054009A for Takeda Chemical Ind., Ltd., August 28, 1991. "PROLONGED RELEASE MICROCAPSULES."
28. WO 00/41,682 A, for LG Chemical, Ltd.; "LIOPHILIC MICROPARTICLES CONTAINING A PROTEIN DRUG OR ANTIGEN AND FORMULATION COMPRISING SAME" Published July 2, 2000. [**Exhibit 28**]
29. A. Berthold et al., "Preparation and Characterization of Chitosan Microspheres as Drug Carrier for Prednisolone Sodium Phosphate as Model for Antiflammatory Drugs", *Journal of Controlled Release*, 1996, 39, 17-25.

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U.S. Serial No... Not Yet Known  
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References 1-25 of the above-identified twenty nine (29) references were submitted as prior art to the United States Patent and Trademark Office on November 8, 2002 for U.S. Serial No. 10/291,327, filed November 8, 2002. Also, reference twenty nine (29) was cited in the March 9, 2004 Office Action for U.S. Serial No. 10/291,327. Accordingly, Applicants will not provide these documents unless otherwise requested by the Examiner. Reference twenty seven (27) will be sent to the Examiner by Express Mail.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 1 of 4

Complete If Known	
Application Number	Not Yet Known
Filing Date	Herewith
First Named Inventor	JIN, Tuo
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	691-C-PCT(CN)-US

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	2	WO 96/40071	12-19-1996	Neocrin Company		
	27	CN1054009A	08-28-1991	Takeda Chemical Ind., Ltd.		
	28	WO 0/041,682 A	07-02-2000	LG Chemical, Ltd.		

<b>Examiner Signature</b>		<b>Date Considered</b>
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Sheet 2 of 4 Attorney Docket Number 691-C-PCT(CN)-US

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Application Number	Not Yet Known
Filing Date	Herewith
First Named Inventor	JIN, Tuo
Art Unit	Not Yet Known
Examiner Name	Not Yet Known

**OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
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	26	PCT International Search Report for JIN, et al, Int'l Application No. PCT/CN/00431, Filed June 3, 2003, Dated August 1, 2003.	
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